

AMENDMENT

U.S. Appln. No. 10/618,963

REMARKS

Claims 26-38 are pending. Claim 26 has been amended to define the magnifying tags as "comprising a nucleic acid sequence of at least two nucleotide bases". Support for this amendment can be found, *inter alia*, at page 15, line 12 of the present specification.

New Claim 39 has been added. Support for new Claim 39 can be found in original Claim 26, and additionally recites that determining the position of a portion of the target molecule is carried out by identifying a label that is incorporated into the portion, where the label indicates the position. Support for this amendment exists throughout the specification as filed, i.e., there are numerous instances referring to obtaining positional information, for example, page 9, line 12. Further, page 45, lines 24 *et seq.*, recites that the target sequence can be labeled or incorporated with elements that are used to derive the position value, and Example 21 (Figure 20) describes an example of this technique.

New Claim 39 is intended to protect the use of positional labels in a sequencing method, where the sequence information can be obtained by any technique (i.e., the sequencing technique is not limited to the "magnifying tag" method of sequencing).

In paragraph 7 on page 9 of the Office Action, the Examiner indicates that Claims 35-38 are objected to, but would be allowable if placed in independent form.

Turning now to the rejections raised by the Examiner.

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In paragraph 4, on page 3 of the Office Action, the Examiner rejects Claims 26-30 under 35 U.S.C. § 102(b) as being anticipated by Keith et al.

In the prior Office Action, Claims 26-29 and 35 had been rejected over Keith et al. In response to that rejection, Claim 26 was amended to include the definition of "magnifying tags" from Claim 30 therein, i.e., Claim 26 was amended to recite "determining the sequence of a portion of said target nucleic acid molecule by identifying magnifying tags associated with the target nucleic acid molecule, wherein said magnifying tags represent a detectable signal or sequence that corresponds to one or more bases of said portion". It was argued that Keith et al does not teach or suggest a method of sequencing utilizing "magnifying tags".

However, it is now the Examiner's position that "magnifying tags" is very broad to include a "detectable signal or sequence that corresponds to one or more bases of said portion". The Examiner contends that Keith et al teaches the use of magnifying tags, i.e., radioisotopes.

In paragraph 5, on page 5 of the Office Action, the Examiner objects to Claims 26-27 and Claims 29-30 under 35 U.S.C. § 102(b) as being anticipated by Shumaker et al.

Specifically, the Examiner notes the APEX method described, for example, on page 348 and in Figure 4 of Shumaker et al. The Examiner contends that since "magnifying tags" can include radioisotopes, Shumaker et al meets this limitation because it teaches the use of radiolabeled deoxynucleotides.

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In paragraph 6, on page 6 of the Office Action, the Examiner rejects Claims 26, 29 and 31-34 under 35 U.S.C. § 102(b) as being anticipated by Strezoska et al.

Specifically, the Examiner states that in Strezoska et al, the magnifying tags are the individual labeled oligonucleotides probes hybridized to the immobilized target nucleic acid sequence (see Panel A of Figure 1 thereof).

For the following reasons, Applicant respectfully traverses the Examiner's rejections.

To clarify the meaning of the term "magnifying tag", and thereby clarify that Keith et al, Shumaker et al or Strezoska et al are not relevant to the Lingvitae "magnifying tag" technology (which involves the physical magnification of the target sequence), Claim 26 has been amended to recite that the magnifying tag "comprises a nucleic acid sequence of at least two nucleotide bases".

This amendment to Claim 26 clarifies the main distinction vis-à-vis Keith et al, Shumaker et al and Strezoska et al, which disclose variations of the standard "Sanger sequencing" technique using labeled (single) nucleotides. There is no disclosure in Keith et al, Shumaker et al or Strezoska et al of the use of a "magnifying tag" that comprises at least two nucleotide bases.

The magnifying tag technology of the present invention has a number of advantages, as detailed, for example, at page 8, paragraph 4; page 10, paragraph 4; and page 11, paragraph 2 of the present application.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Keith et al or

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Shumaker et al or Strezoska et al, and thus request withdrawal of the Examiner's rejections.

As to new Claim 39, the prior art sequencing methods require physical separation of fragments to identify the position (terminus) of each fragment (Sanger sequencing), or require a number of overlapping fragments to be produced in order to construct the sequence (e.g., as in Keith et al). There is no disclosure of a sequencing method wherein a positional label is incorporated into the sequence fragment(s), as recited in Claim 39.

The invention defined by Claim 39 takes a completely different approach to sequencing, compared to the prior art methods, and offers the surprising advantage that the position of each sequenced fragment can be determined without requiring time-consuming analysis involving comparison to other sequences, to complete sequence re-construction. The concept of incorporating into a sequenced fragment a label that instantly identifies the position of the fragment in the target molecule is not suggested by the prior art, which focuses entirely on post-sequencing re-construction of the target sequence by comparison of all sequenced fragments.

In view of the amendments to the claims and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

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The Examiner is invited to contact the undersigned at the below-listed number on any questions which might arise.

Respectfully submitted,

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